K001806

SEP 1 2 2000

Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

1. **Submitter's name, address, telephone number, contact person, and data summary prepared:**

   a. Millennium Biomedical Inc.
   360 East Bonita Avenue
   Pomona, California 91767
   Phone: (909)-621-7646
   Fax: (909)-621-7556

   b. Contact Person: Jerry Kaeni
   President

   c. Date Summary Prepared: July 26, 2000

2. **Name of device, including trade name and classification name:**

   a. Trade/Proprietary Name: MBI Blades

   b. Classification Name: Keratome, AC-Powered, and/or Blades

3. **Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:**

Company	Device	510(k) No.	Date Cleared
Bausch & Lomb Surgical (B&LS) (formally Chiron Vision Corp)	Automatic Corneal Shaper Surgical Instrument	K941550	11/22/1994
Surgistar Inc.	Microkeratome Blade	K992978	11/16/1999
Surgin Surgical Instrumentation, Inc.	Accublade (ACS Model) MK8507	K994015	03/15/2000

4. **A description of the device that is the subject of the 510(k), including explanation of how device function, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The MBI is a replacement blade to be used with the Chiron Automatic Corneal Shaper to cut cornea in the form of a hinged flap. The MBI blade is a single-use only, disposable device. The Blade material is similar to that used in predicate devices (stainless steel).

5. **A statement of intended use:**

The MBI Blade is intended to be used as a replacement blade for the Chiron Automatic Cornel Shaper to cut cornea in the form of a hinged flap.

6. **A statement of how the technological characteristics of the device compare to those of the predicate or legally marketed devices:**

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS OF DEVICE

CHARACTERISTICS	B&L AUTOMATIC CORNEAL SHAPER BLADE (PREDICATE)	SURGISTAR MICROKERATOME BLADE (PREDICATE)	MBI BLADE
Intended Use	Indicated for use with the Automatic Corneal Shaper by surgeons to cut cornea in the form of a hinged flap in LASIK refractive surgery procedures	Indicated for use with the Automatic Corneal Shaper by surgeons to cut cornea in the form of a hinged flap in LASIK refractive surgery procedures	Indicated for use as a replacement blade for the CHIRON Automatic Corneal Shaper
Operating Principle	Blade is held in electrically driven oscillating head (provided by original equipment manufacturer) which guides blade across the cornea	Blade is held in electrically driven oscillating head (provided by original equipment manufacturer) which guides blade across the cornea	Blade is held in electrically driven oscillating head (provided by original equipment manufacturer) which guides blade across the cornea
Blade Design	Single edge blade	Single edge blade	Single edge blade
Sterilization Method	EO	Cobalt 60 radiation	Cobalt 60 radiation
Materials	Low carbon stainless steel	Low carbon stainless steel	Low carbon stainless steel
Patient Contact Portion of Device	Blade	Blade	Blade

DIMENSIONAL EQUIVALENCY CHART

ATTRIBUTE	B&L AUTOMATIC CORNEAL SHAPER BLADE (PREDICATE)	SURGISTAR MICROKERATOME BLADE (PREDICATE)	MBI BLADE
Length	0.448"	0.450" ± 0.010"	0.450" ± 0.010"
Width	0.313"	0.313" ± 0.003"	0.3146" ± 0.0005"
Thickness	0.0102"	0.010" ± 0.0003"	0.010" ± 0.0003"
Bevel	13°	11.5° ± 1°	13°
Mounting hole length	0.2805"	0.2805" ± 0.0005"	0.2805" ± 0.0005"
Mounting hole width	0.0866"	0.0866" ± 0.0005"	0.0866" ± 0.0002"
Mounting hole radius	0.0433"	0.0433" ± 0.0005"	0.0433" ± 0.0010"
Sharpness verification	• Inspected at 100X by Scanning Electron Microscope		• Inspected at 100X by Scanning Electron Microscope • Clinically tested and verified in China and India

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2000

Mr. Jerry Kaeni
President
Millennium Biomedical, Inc.
360 E. Bonita Avenue
Pomona, CA 91767

Re: K001806
Trade Name: Millennium Blades- MBI 100
Regulatory Class: I
Product Code: 86 HNO
Regulation: 886.4370
Dated: June 12, 2000
Received: June 15, 2000

Dear Mr. Kaeni:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K001806

Device Name: Millennium Blade (MB100)

Indications for Use:

The Millennium Blade is a replacement blade for Chiron ACS Microkeratome.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K001806

Prescription Use x **OR Over-The-Counter Use** _____

(Per 21 CFR 801.109)